



The National Voice for Direct-Care RNs

WASHINGTON DC
8455 Colesville Road
Suite 1100
Silver Spring MD 20910
phone: 800-287-5021
fax: 240-235-2019

OAKLAND
155 Grand Avenue
Suite 100
Oakland CA 94612
phone: 800-504-7859
fax: 510-663-1625

May 23, 2025

The Honorable Martin Adel Makary, Commissioner
U.S. Department of Health and Human Services
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Members of the Vaccines and Related Biological Products Committee (VRBPAC) for the
Food and Drug Administration

**Re: Docket No. FDA-2025-N-1146, Vaccines and Related Biological Products; Notice
of Meeting; Establishment of a Public Docket; Request for Comments**

Dear Commissioner Makary and VRBPAC Members:

On behalf of more than 225,000 registered nurse (RNs) members, National Nurses United (NNU), the largest labor union and professional association for RNs in the United States, submits these comments in response to the request for comments regarding the public meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) on May 22, 2025.

NNU values the Food and Drug Administration's (FDA) commitment to ensuring the safety and effectiveness of vaccines to protect public health. VRBPAC's work to evaluate data on the safety and effectiveness of vaccines and provide expert input into FDA vaccine policy is key to protecting public health. However, on May 20, 2025, FDA Commissioner Makary and Center for Biologics Evaluation and Research Director Vinay Prasad published a new framework for Covid-19 vaccination that would limit access to Covid-19 boosters to only those over 65 years of age and those at high risk for severe Covid-19.¹ While the framework is not yet official FDA policy, it is concerning that this framework was published without input and insight from VRBPAC experts and that VRBPAC was not asked to discuss the framework at the May 22, 2025 meeting.

As the nation's frontline health care workforce, RNs are acutely aware of the importance that vaccines play in safeguarding the health of our patients and communities. Vaccines are an important part of a multilayered approach to infection control—indeed, childhood vaccination has been estimated to save 154 million lives globally over the past 50 years² and the Covid-19 vaccines are estimated to have saved 19.8 million lives in the first year of

¹ Prasad, V. and Makary, M.A., "An Evidence-Based Approach to Covid-19 Vaccination," New England Journal of Medicine, May 20, 2025.

² Shattock, A.J., Johnson, H.C., et al., "Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization," The Lancet, 2024, 403(10441): 2307-16.

the pandemic alone.³ NNU urges the FDA and VRBPAC to ensure that Covid-19 vaccines—which have been proven to be safe and effective⁴—remain available and accessible to RNs, other health care workers, and patients.

I. Covid-19 vaccines have saved millions of lives and are a critical part of protecting public health across all age groups.

Covid-19 vaccines have been shown to protect against severe disease, hospitalization, and death. One study found that the 2024 – 2025 Covid-19 vaccine was 33 percent effective in preventing Covid-related emergency department or urgent care visits among adults aged ≥ 18 years and about 46 percent protective against hospitalizations among immunocompetent older adults.⁵ Another study found that Covid-19 vaccine boosters were associated with a 75.1 percent reduction in severe disease.⁶

However, the new Covid-19 vaccine framework published by Commissioner Makary and Director Prasad would restrict access to Covid-19 boosters to only those over 65 years or at high risk for severe Covid-19, erroneously assuming that Covid-19 only impacts elderly and high-risk populations. To the contrary, Covid-19 continues to cause significant morbidity and mortality across all age groups in the United States, as was recognized during the May 22, 2025 VRBPAC meeting. Preliminary estimates from the U.S. Centers for Disease Control and Prevention found that between 260,000 and 430,000 Covid-19-associated hospitalizations and nearly 47,000 Covid-19-deaths occurred since 2024, across all age groups including pediatric populations.^{7,8} Waning immunity from vaccines and the emergence of new variants renders people vulnerable to severe disease, long-term health complications, and death. The risk of long Covid—a condition that impacts approximately 7 percent of adults with Covid-19⁹—increases with each subsequent infection¹⁰ and is a risk that cannot be ignored.

³ Mellis, C., “Lives saved by COVID-19 vaccines,” J Paediatr Child Health, Sept 20, 2022.

⁴ CDC, “COVID Data Tracker,” May 10, 2024 <https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness> (Accessed May 23, 2025).

⁵ Link-Gelles, R., Chickery, S., et al., “Interim Estimates of 2024–2025 COVID-19 Vaccine Effectiveness Among Adults Aged ≥ 18 Years — VISION and IVY Networks, September 2024–January 2025,” MMWR, Feb. 27, 2025;74:73–82.

⁶ Chemaitelly, H., Ayoub, H. H., et al., “Long-term COVID-19 booster effectiveness by infection history and clinical vulnerability and immune imprinting: a retrospective population-based cohort study,” The Lancet Infectious Diseases, July 2023, 23(7), 816-827.

⁷ CDC, “Preliminary Estimates of COVID-19 Burden for 2024-2025,” December 6, 2024, <https://www.cdc.gov/covid/php/surveillance/burden-estimates.html> (Accessed May 22, 2025).

⁸ CDC, “COVID Data Tracker,” May 22, 2025, <https://covid.cdc.gov/covid-data-tracker> (Accessed May 22, 2025).

⁹ KFF, “Long COVID Rates Appear to be Stabilizing, Affecting About 1 in 10 Adults Who Have Had COVID,” April 9, 2024, <https://www.kff.org/coronavirus-covid-19/press-release/long-covid-rates-appear-to-be-stabilizing-affecting-about-1-in-10-adults-who-have-had-covid/> (Accessed May 23, 2025).

¹⁰ Peluso, MJ., Deeks, SG., “Mechanisms of long COVID and the path toward therapeutics,” Cell, October 3, 2024; 187(20):5500-29.

II. Optimal infection control protections, including Covid-19 vaccines, are necessary to protect the health and safety of RNs, other health care workers, and patients.

Covid-19 poses a significant occupational risk to RNs and other health care workers, who continue to be on the frontlines of the Covid-19 response. Studies have consistently documented higher rates of Covid-19 infections and disease among health care workers than the general population.^{11,12}

Optimal protection of health care workers through robust infection control measures, including optimal PPE, ventilation, and access to Covid-19 vaccines and boosters, is necessary in order for health care workers to safely provide care for patients.^{13,14} Indeed, Covid-19 vaccination and boosters have been shown to prevent hospitalization and infection with symptomatic Covid-19¹⁵ and to reduce time off work caused by infection among health care workers.¹⁶ Yet, the new Covid-19 vaccine framework proposed by Commissioner Makary and Director Prasad ignores the increased occupational exposure risk that RNs and other health care workers continue to face. This omission would have a severe and negative impact on the safety of our RNs and health care workers.

III. Long Covid remains a serious public health crisis for which there is no treatment or cure.

Public health measures regarding Covid-19 must take into account the significant risk of long Covid. Long Covid is a serious condition that can impact all major organ systems, causing debilitating symptoms that can last from a few weeks to several years following a Covid-19 infection, including mild initial infections.¹⁷ Long Covid has been estimated to

¹¹ Nguyen, L.H., D.A. Drew, et al., “Risk of COVID-19 among front-line health-care workers and the general community: a prospective cohort study,” *The Lancet Public Health*, July 31, 2020, 5(9): e475-83.

¹² Barrett, E.S., Horton, D.B., Roy, J. et al., “Prevalence of SARS-CoV-2 infection in previously undiagnosed health care workers in New Jersey, at the onset of the U.S. COVID-19 pandemic,” *BMC Infectious Diseases*, November 16, 2020, 20(1):853.

¹³ Daniel W, Nivet M, et al., “Early evidence of the effect of SARS-CoV-2 vaccine at one medical center,” *New England Journal of Medicine*, March 23, 2021, 384:1962–1963.

¹⁴ Keehner, J., Horton, L.E. et al., “SARS-CoV-2 Infection after Vaccination in Health Care Workers in California,” *New England Journal of Medicine*, March 23, 2021, 384, 1774–1775.

¹⁵ Galgut, O., Ashford, F., et al., “COVID-19 vaccines are effective at preventing symptomatic and severe infection among healthcare workers: A clinical review,” *Vaccine X*, August 2024, 20:100546.

¹⁶ Maltezou, H.C., Gamaletsou, M.N., et al., “Effectiveness of COVID-19 booster vaccination, morbidity and absenteeism among healthcare personnel during the 2022–2023 season dominated by Omicron BA.5 and BA.2 subvariants,” *Vaccine*, 2024, 42(17): 3693-8

¹⁷ CDC, “Long COVID Basics,” Feb 3 2025, <https://www.cdc.gov/covid/long-term-effects/index.html> (Accessed May 23, 2025).

impact 7 percent of the population in the United States.¹⁸ The risk of long Covid increases with each subsequent infection.¹⁹

Covid-19 vaccines and boosters have been shown to decrease the risk of long Covid.^{20,21} However, the new framework proposed by Commissioner Makary and Director Prasad ignores the risk of long Covid entirely. This is a dangerous and problematic omission, especially for RNs and other health care workers who are at particularly high risk of developing long Covid.²² NNU's 2024 infectious diseases survey documented significant impacts of long Covid experienced by RNs, including fatigue, memory or concentration difficulties, muscle pain, headaches or migraines, shortness of breath, and other symptoms.²³ For 50 percent of RNs, long Covid symptoms lasted longer than six months and a majority of RNs with long Covid reported that their symptoms have affected their ability to work (73.5 percent) and their daily activities outside of work (86.9 percent).²⁴ Maintaining access to Covid-19 vaccines for RNs and other frontline health care workers at high risk of exposure to and infection with Covid-19 in the workplace is essential to protecting their health at work.

In Conclusion

Vaccines, including Covid-19 vaccines, play an essential role in protecting public health and workplace health and safety for RNs and other health care workers. Limiting access to and availability of lifesaving Covid-19 vaccines unnecessarily puts lives at risk. With health equity being central to the practice of nursing, nurses will continue to advocate for strong public health measures to protect and foster patients' health and healing, at the bedside and beyond.

Sincerely,



Nancy Hagans, RN
President, National Nurses United

¹⁸ KFF, "Long COVID Rates Appear to be Stabilizing, Affecting About 1 in 10 Adults Who Have Had COVID," April 9, 2024, <https://www.kff.org/coronavirus-covid-19/press-release/long-covid-rates-appear-to-be-stabilizing-affecting-about-1-in-10-adults-who-have-had-covid/> (Accessed May 23, 2025).

¹⁹ Peluso, MJ., Deeks, SG., "Mechanisms of long COVID and the path toward therapeutics," Cell, October 3, 2024; 187(20):5500-29.

²⁰ Xie, Y., Choi, T., et al., "Postacute Sequelae of SARS-CoV-2 Infection in the Pre-Delta, Delta, and Omicron Eras," NEJM, 2024, 391: 515-25.

²¹ Hedberg, P., van der Werff, S.D., et al., "The Effect of COVID-19 Vaccination on the Risk of Persistent Post-COVID-19 Condition: Cohort Study," The Journal of Infectious Diseases, March 12, 2025.

²² Al-Oraibi, A., Woolf, K., et al., "Global prevalence of long COVID and its most common symptoms among healthcare workers: a systematic review and meta-analysis," BMJ Public Health, April 16, 2025.

²³ National Nurses United, "NNU Infectious Diseases Survey: November 2024 Preliminary Results," November 13, 2024, <https://www.nationalnursesunited.org/infectious-diseases-survey-november-2024-preliminary-results> (Accessed May 22, 2025).

²⁴ Ibid.